GaitSmart assessment and vGym personalised exercise rehabilitation programme for people with gait and mobility issues

Medtech innovation briefing
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Summary

- The technology described in this briefing is GaitSmart. It is used to monitor limb movement in people with gait and mobility issues.

- The innovative aspects are that the GaitSmart programme can be provided by a healthcare assistant in any setting. Quantitative objective data can be tracked over time to tailor interventions for each user.

- The intended place in therapy would be in addition to current gait assessment in older people at risk of falling, people with hip or knee osteoarthritis and people with hip or knee replacements.
The main points from the evidence summarised in this briefing are from 5 studies: 1 prospective cohort study, 2 validation studies and 2 studies that used the technology to assess gait. This included a total of 669 older people at risk of falling, people with knee osteoarthritis and people with hip or knee replacements. They show that GaitSmart is as effective as current gait assessment for these people.

Key uncertainties around the evidence are that the outcomes used are difficult to compare with current methods used in standard care in the NHS. The specific costs of current methods of gait assessment are not available for comparison. There is also no published data on randomised controlled trials comparing the technology with standard care.

Experts advised that the technology may improve the identification of gait issues and engagement with rehabilitation exercise plans. They also said that healthcare professions would need training and should recognise the risk of exacerbating any problems.

The cost of GaitSmart is £67 per user (excluding VAT). This includes 4 separate assessments and access to the vGym rehabilitation programme. The cost of standard care varies widely depending on specific patient groups. GaitSmart would be expected to be an additional cost on top of standard care, with the potential for improved patient outcomes to offset some of these additional costs.

The technology

GaitSmart (Dynamic Metrics) is a sensor-based digital technology that monitors limb movement. Three patient groups have been identified for this technology: older people at risk of falling, people with hip or knee osteoarthritis and people with hip or knee replacements. The technology requires 7 sensors to be placed on the pelvis, thigh and calf on either side of the body, as well as the base of the spine. Objective measurements are taken while walking to identify any problems with gait. The test takes 10 minutes to complete and can be done by a healthcare assistant in a variety of settings. Information from the sensors is automatically processed to produce a colour-coded report that helps the healthcare professional to understand the gait issue and its severity. The technology can be used with the integrated app vGym to provide a personalised rehabilitation programme, consisting of 6 exercises, to help improve mobility. The app provides photos and descriptions of each exercise. Each person is expected to do 4 GaitSmart tests once allocated to the programme after referral by their GP or the hospital. Reports at each session assess if there have been any improvements and then exercises are altered
Innovations

The company claims that the GaitSmart programme can be provided by a healthcare assistant in any setting, whereas current practice is for people to attend a falls clinic or intensive rehabilitation training in a hospital. The GaitSmart report provides the patient and clinician with objective data that can be tracked over time. The data is used to inform treatment choice by tailoring an exercise programme for the user through the vGym app.

Current care pathway

Older people who have suffered a fall or report recurring falls, or have abnormal gait or balance, are normally offered a multifactorial falls risk assessment by a healthcare professional in a specialist falls service. Interventions are tailored to each individual and usually include exercise, strength and balance training, home hazard assessment, vision assessment and medication review.

People with hip or knee osteoarthritis do not have their gait assessed specifically in clinical practice, but holistic assessment and patient information is provided. This includes pain assessment and advice on exercise.

People who have had a hip or knee replacement are given advice on pre-operative rehabilitation. This includes exercises to do before and after surgery to aid recovery. Rehabilitation after the procedure is usually self-directed based on advice received before discharge.

The following publications have been identified as relevant to this care pathway:

- NICE guideline on falls in older people: assessing risk and prevention
- NICE guideline on osteoarthritis: care and management
- NICE guideline on joint replacement: hip, knee and shoulder
- NICE clinical knowledge summary on falls risk assessment
- NICE clinical knowledge summary on osteoarthritis
Population, setting and intended user

GaitSmart is intended to be used in older people at risk of falling, people with hip or knee osteoarthritis and people with hip or knee replacements.

The company notes that the GaitSmart programme can be provided in any setting including GP surgeries, outpatient settings and community centres.

GaitSmart is intended to be used by a healthcare assistant and additional training is needed to use the technology.

Costs

Technology costs

The cost of GaitSmart is £67 per user. This includes 4 sessions of GaitSmart tests, the vGym rehabilitation exercise programme and the cost of employing a healthcare assistant to do the test. The cost of each GaitSmart session is £10 (£40 for 4 sessions) and the cost of employing a band 3 healthcare assistant for four 25-minute sessions is estimated at £27. There is an additional one-off cost of £1,000 for loan of the GaitSmart system to the NHS and training. The minimum number of GaitSmart sessions needed per month is 100.

Resource consequences

GaitSmart has been used in the NHS in a clinical trial context. Most services do not have a formal pathway to assess gait in older people at risk of falling, people with hip or knee osteoarthritis and people with hip or knee replacements. Clinicians would need to be trained to use the technology and read the report; training is offered for an additional one-off cost.

GaitSmart would be used in addition to current assessment of people with gait problems. The company claims that GaitSmart would improve gait assessment and choice of intervention, as well as increasing access to objective gait analysis. This may result in benefits from improved patient outcomes. The potential to have a lower grade of staff read
the reports could lead to reduced costs.

**Regulatory information**

GaitSmart is a CE-marked class I medical device.

No manufacturer field safety notices or medical device alerts for this technology have been identified.

**Equality considerations**

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

Age and disability are protected characteristics. People with hip or knee osteoarthritis and hip or knee replacements may be protected under the disability element of the Equality Act. This is because their condition is likely to have long-term adverse effects on their ability to do normal day-to-day activities.

People who have difficulty accessing or using a device for the GaitSmart report and vGym exercise programme may be excluded from being able to use this technology.

**Clinical and technical evidence**

A literature search was carried out for this briefing in accordance with the interim process and methods statement. This briefing includes the most relevant or best available published evidence relating to the clinical effectiveness of the technology. Further information about how the evidence for this briefing was selected is available on request by contacting mibs@nice.org.uk.

**Published evidence**

There is a small body of evidence for the GaitSmart system. The most up-to-date studies that had large populations and focused on the 3 outlined indications were prioritised. Evidence from 5 studies is summarised in this briefing.
The studies in the briefing include a prospective cohort study (Hodgins et al. 2020), 2 validation studies in which GaitSmart was compared with current methods of gait analysis (Van Helvoort et al. 2021 and Zügner et al. 2019) and another study that used the technology to assess gait in people with hip replacements (Rahman et al. 2015). One study (Monda et al. 2015) used GaitSmart to assess gait in different age groups. The size of the population in these studies ranged from 49 to 284.

The clinical evidence and its strengths and limitations is summarised in the overall assessment of the evidence.

**Overall assessment of the evidence**

GaitSmart has been used in studies assessing older people at risk of falling, people with hip or knee osteoarthritis and people with hip or knee replacements. Gait has also been assessed in people with other indications such as haemophilia and ankle fractures.

One validation study (Van Helvoort et al. 2021) compared GaitSmart with radiographic assessment and patient-reported outcome measures in people with knee osteoarthritis. Two other studies (Zügner et al. 2019 and Monda et al. 2015) compared GaitSmart with an optical tracking system, in people with hip replacements and in an active population. More studies are needed to compare GaitSmart parameters with standard care. This will highlight which aspects of assessment and treatment can be informed by the technology in practice. A strength of the evidence base is that studies have been done in settings relevant to NHS clinical practice.

The company states that the vGym rehabilitation programme can be used after assessment with GaitSmart to improve gait in each of the 3 indications. Limited evidence on the vGym rehabilitation programme was found. GaitSmart would be used as a tool to inform treatment choice and improve gait over time. So, longer comparative follow-up studies are needed to show how analysis with GaitSmart improves patient outcomes compared with standard care.

**Hodgins et al. (2020)**

**Study size, design and location**

A prospective cohort study of 121 older people who have had an injurious fall in the UK.
Intervention and comparator

GaitSmart, no comparator.

Key outcomes

Five parameters were analysed for everyone before and after the GaitSmart intervention. The Edmonton Frail Scale (EFS) was used to analyse frailty, with a maximum score of 17 representing the highest level of frailty. Fear of falling was measured using the short form Falls Efficacy Scale-International (FES-I). Gait score was derived through measuring gait kinematics using the GaitSmart system. A walking aid score was calculated using a 4-tier scoring system, based on the level of aid needed.

Mean EFS score decreased from 7.6 to 5.6; 71% of people showed improvement after intervention. Mean FES-I score decreased from 14.9 to 11.7, with 75% improvement. Gait score increased from 26.1% to 46.3%; improvement was seen in 76% of people. The walking aid score decreased from 2.5 to 1.8 with 39.7% improvement. Average walking speed increased from a mean of 0.46 m/s to 0.62 m/s; 80.5% of people experienced improvement.

Strengths and limitations

There was no comparator intervention in this study, so the gait score was correlated to EFS and FES-I to assess its use as an objective parameter. After the intervention, there was a good correlation between gait score and EFS (r=0.58) and a moderate correlation with FES-I (r=0.50). The study setting was an NHS trust, and the study population was reflective of the population seen in clinical practice.

Van Helvoort et al. (2021)

Study size, design and location

Prospective validation study of 284 people with radiographic knee osteoarthritis to assess motion with GaitSmart and how parameters relate to radiographic assessment. The study was done in France, the Netherlands, Norway and Spain.
Intervention and comparator

GaitSmart, compared with radiography.

Key outcomes

Principal component analyses (PCA) were done to explore the relationship between GaitSmart parameters alone, and in addition to radiographic parameters and patient-reported outcome measures. Logistic and linear regression analyses were done to analyse the relationship of GaitSmart with the presence and severity of radiographic osteoarthritis (ROA).

PCA of GaitSmart parameters showed 5 primary variables:

- range of motion in hips
- difference in range of motion of each hip
- range of motion of knees and calves
- differences in range of motion of knees and calves during swing phase
- range of motion of knees during stance phase.

Patient-reported outcome measures and radiographic parameters were found to measure different elements of disease status. There were 159 people who had ROA. Logistic regression analysis showed that the $R^2$ value increased from 0.075 to 0.150 when adding GaitSmart data to the model with demographics and patient-reported outcome measures to detect ROA. This improved the association with presence of ROA; sensitivity was 71% and specificity was 52%.

Strengths and limitations

The authors stated that a limitation of the study is that people with a high probability of structural or pain progression were selected. This may restrict the generalisability of results. Another limitation is the lack of follow-up data because it is highly relevant to evaluate whether the GaitSmart parameters have any prognostic value. This study showed that specific GaitSmart parameters may provide additional value to assess osteoarthritis compared with radiography and patient-reported outcome measures.
Monda et al. (2015)

Study size, design and location

Cohort study of GaitSmart compared with an optical tracking system to assess age-related changes in gait of an active population in the UK.

Intervention and comparator

GaitSmart, compared with an optical tracking system (Coda Motion).

Key outcomes

Statistical analysis showed significant differences between the different age groups for all parameters. For all the angle data (knee range of motion, knee stance, thigh range of motion, shank range of motion) the over 80 group was significantly different from all others except for knee stance angle when compared with the group aged 70 to 79. Stride duration was a mean of 1.03 seconds in the under 30 age group compared with a mean of 1.14 seconds in the over 80 group. However, stride duration in the over 80 group was not significantly different to the 60 to 69 and 70 to 79 age groups. The relationship between the angles and age were found to be non-linear, with little change happening until age 70 and rapid changes after the age of 80. There was no significant difference found between the estimates of knee range of motion between GaitSmart and the optical tracking systems. The precision of the estimates was similar for all parameters.

Strengths and limitations

This study did not measure the effectiveness of GaitSmart assessment in improving gait but was an exploratory study to assess differences in gait between age groups in an active population. By separating the study population into age groups, significant timepoints for changes in gait could be identified. GaitSmart assessment was validated by comparing accuracy and precision with the optical tracking system.
Zügner et al. (2019)

Study size, design and location
Validation study of GaitSmart compared with an optical tracking system for gait assessment in 49 people with hip replacements in Sweden.

Intervention and comparator
GaitSmart, compared with an optical tracking system (Oqus 4).

Key outcomes
Pelvic rotations and hip and knee flexion-extension motions were measured and compared between the 2 systems. The comparison between the 2 methods showed no significant difference for mean pelvic tilt range (4.9 degrees to 5.4 degrees) and mean knee flexion range (54.4 degrees to 55.1 degrees) on either side (p>0.7). GaitSmart recorded significantly less hip flexion on both sides compared with Oqus 4 (34 degrees to 34.4 degrees compared with 36.7 degrees to 37.7 degrees, p<0.001).

Strengths and limitations
The accuracy of data seen by using GaitSmart has been validated based on the accuracy of the optical tracking system. Optical tracking systems can be used for gait analysis in people who have had a hip replacement, but GaitSmart can be used in different environments and takes less time to do.

Rahman et al. (2015)

Study size, design and location
Study using GaitSmart for gait assessment in 79 people who were having or had had a knee replacement and 29 age-matched controls in the UK.

Intervention and comparator
GaitSmart, no comparator.
Key outcomes

There were 74 people with knee replacements, including 29 at the pre-operative stage, 17 at 8 weeks after operation and 28 at 52 weeks after operation. Mean values of knee, shank and thigh angles were collected during the gait cycle. The most statistically significant change from the pre-operative group to 52 weeks after operation was knee swing (42.51 degrees to 50.64 degrees). Stride duration decreased from 1.31 seconds to 1.24 seconds, but this change was not statistically significant. Statistical analysis showed that there was a significant difference in several gait variables when comparing the patient groups with 29 age-matched controls who had not had a knee replacement (F=34.66, p<0.001).

Strengths and limitations

This study was not a validation study of GaitSmart and did not include a comparator intervention. The primary differentiating factor between patients and controls was knee flexion during stance, a general characteristic of osteoarthritic gait that is maintained after surgery. The authors concluded from their use of the technology that it can identify patients who may benefit from additional rehabilitation.

Sustainability

The company claims the technology will have a lower environmental impact compared with current standard practice. This is because of reduced travel and more efficient use of NHS resources. There is no published evidence to support these claims.

Recent and ongoing studies


Expert comments

Comments on this technology were invited from clinical experts working in the field and relevant patient organisations. The comments received are individual opinions and do not
represent NICE's view.

Three out of 4 experts were familiar with or had used this technology before.

**Level of innovation**

Three of the experts considered this technology to be innovative compared with standard care. The other expert stated that gait analysis is not new, but the technology has adapted it for use in a clinical setting. Current rehabilitation provision involves a short course of physiotherapy, a video consultation or an information sheet. One expert explained that many people have inadequate rehabilitation or no post-operative rehabilitation at all. GaitSmart allows engagement with a healthcare professional, objective gait assessment and regular follow up, which includes patient-centred exercises.

**Potential patient impact**

All of the experts mentioned the potential of this technology in engaging people to take a more active approach in their rehabilitation and to chart their own progress over time. As the treatments are tailored to each individual through the personalised exercise plan, people are motivated to follow the programme and less physiotherapist involvement is needed in the community. Two of the experts described how the technology provides an opportunity to identify issues earlier, which could eliminate the need for surgical intervention or improve fitness before surgery for those having operations. The experts mentioned several groups that could particularly benefit from using the technology, such as people having recurring falls, people with degenerative joint disease, people awaiting knee and hip procedures and people who have already had surgery.

**Potential system impact**

Three of the experts commented that the technology could change the current treatment pathway. GaitSmart could allow people to have dedicated rehabilitation therapy before surgery, which could lead to improved health outcomes and decreased hospital stay. The technology can also be used in primary care or home settings, which could increase the efficiency of resource use. One of the experts anticipates that the technology will increase costs. The other 3 experts suggested that the intervention could decrease costs overall by improving patient outcomes, allowing treatment at an earlier timepoint, providing patients with the ability to work on their own rehabilitation and reducing the number of hospital
The experts agreed that no changes are needed to existing facilities except for the initial purchase of the device. The assessment would take place in most district general hospitals in the UK, as well as in outpatient settings or in the community. Training is needed for the healthcare professionals using the device to ensure accurate assessment is done. One expert noted that this can be provided by the company and completed in one morning. Another expert highlighted that physiotherapy and exercise can exacerbate underlying healthcare issues when done incorrectly, but there have been no adverse cases in relation to GaitSmart. The experts were not aware of any other competing technologies available to the NHS that have a similar function.

Expert commentators

The following clinicians contributed to this briefing:

- Professor Iain McNamara, consultant orthopaedic surgeon, Norfolk and Norwich University Hospitals NHS Foundation Trust. Is currently trialling the device as part of a research project.

- Dr Julian Brown, general practitioner and clinical lead, Litcham Health Centre and NHS Norfolk and Waveney Clinical Commissioning Group. Did not declare any interests. Working collaboratively with the company to improve patient outcomes.

- Mr Michael Kelly, consultant orthopaedic surgeon, North Bristol NHS Trust. Did not declare any interests.


Development of this briefing

This briefing was developed by NICE. The interim process and methods statement sets out the process NICE uses to select topics, and how the briefings are developed, quality-assured and approved for publication.